



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/815,707	04/02/2004	Alan K. Smith	250512US	9727
22850	7590	09/22/2004	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			BELYAVSKYI, MICHAEL A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/815,707

Applicant(s)

SMITH ET AL.

Examiner

Michail A Belyavskyi

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Art Unit: 1644

DETAILED ACTION

1. Claims 1-45 are pending.

Restriction Requirement

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
 - I. Claims 2, 34 and 42 drawn to a method for obtaining human lineage committed hematopoietic cells, mesenchymal cells, keratinocytes, fibroblasts, hepatocytes, neural cells, osteoblasts or osteoclasts classified in Class 435, subclass 375
 - II. Claims 3, 35 and 43 drawn to a method for obtaining human lineage committed stem cells, progenitor cells, myeloid cells or stromal cells classified in Class 435, subclass 375
 - III. Claims 4, 5, 36, 37, 44 and 45 drawn to a method for obtaining human lineage committed dendritic cells or non-myeloid mature cells which are other than stromal cells, classified in Class 435, subclass 375
 - IV. Claim 16 drawn to a composition of human lineage committed hematopoietic cells, mesenchymal cells, keratinocytes, fibroblasts, hepatocytes, neural cells, osteoblasts or osteoclasts classified in Class 435, subclass 325.
 - V. Claim 17 drawn to a composition of human lineage committed human lineage committed stem cells, progenitor cells, myeloid cells or stromal cells classified in Class 435, subclass 325.
 - VI. Claims 18 and 19 drawn to a composition of human lineage committed dendritic cells or non-myeloid mature cells which are other than stromal cells, classified in Class 435, subclass 325.
 - VII. Claim 25 drawn to a method for treating a human patient in need, comprising administering a composition of human lineage committed hematopoietic cells, mesenchymal cells, keratinocytes, fibroblasts, hepatocytes, neural cells, osteoblasts or osteoclasts, classified in Class 424, subclass 93.1.
 - VIII. Claims 26, drawn to a method for treating a human patient in need, comprising administering a composition of human lineage committed stem cells, progenitor cells, myeloid cells or stromal cells, classified in Class 424, subclass 93.1.

Art Unit: 1644

IX. Claims 27 and 28, drawn to a method for treating a human patient in need, comprising administering a composition of human lineage committed dendritic cells or non-myeloid mature cells which are other than stromal cells, classified in Class 424, subclass 93.1.

Claims 1, 7-14, 33, 38-41 are linking claims and will be examined along with claims of Groups I-III if one of Groups I-III is elected.

Claims 1 and 6 are linking claims and will be examined along with claims of Group I

Claims 15 and 20-23 are linking claims and will be examined along with claims of Groups IV-VI if one of Groups IV-VI is elected.

Claims 24 and 29-32 are linking claims and will be examined along with claims of Groups VII-IX if one of Groups VII-IX is elected.

4. Groups I-III and VII-IX are different methods. These inventions are different with respect to ingredients, method steps, and endpoints which require non-coextensive searches; therefore, each method is patentably distinct.

5. Groups IV-VI are different products. These inventions differ with respect to their structures physicochemical properties, which require non-coextensive searches; therefore each product is patentably distinct.

6. Groups IV-VI and VII-IX are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the human lineage committed can be used to produced conditioning media in addition to the methods of treating.

7. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Moreover, a prior art search also requires a literature

Art Unit: 1644

search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product (Groups IV- VII) and process claims (Group I -III). If applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

A telephone call was made to Daniel Perreira to request an oral election to the above restriction requirement, but did not result in an election being made.

Art Unit: 1644

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/ 272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/ 272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskiy, Ph.D.
Patent Examiner
Technology Center 1600
September 20, 2004


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600